(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(19) World Intellectual Property Organization
International Bureau

(43) International Publication Date
27 September 2001 (27.09.2001)

PCT

(10) International Publication Number
WO 01/70096 A1

(51) International Patent Classification[7]: A61B 1/01, 1/31

(21) International Application Number: PCT/IE01/00038

(22) International Filing Date: 23 March 2001 (23.03.2001)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
2000/0225 23 March 2000 (23.03.2000) IE
2000/0559 11 July 2000 (11.07.2000) IE

(71) Applicant *(for all designated States except US)*: **ATROPOS LIMITED** [IE/IE]; Unit 4, Sunnybank Centre, Bray, County Wicklow (IE).

(72) Inventors; and

(75) Inventors/Applicants *(for US only)*: **BUTLER, John** [IE/IE]; 16 Holly Park, Blackrock, County Dublin (IE). **BRENNAN, Edmund** [IE/IE]; 14 The Willows, Monkstown Valley, County Dublin (IE). **BONADIO, Frank** [US/IE]; 2 Martello Terrace, Bray, County Dublin (IE). **BUCKLEY, Declan** [IE/IE]; 38 Greenpark Meadows, Mullingar, County Westmeath (IE). **GILL, Aoibheann** [IE/IE]; Rathcline, Lanesboro, County Longford (IE). **YOUNG, Derek, William** [IE/IE]; 3 Cloister Way, Carysfort Avenue, Blackrock, County Dublin (IE). **REID, Alan** [IE/IE]; 7 Kincora Drive, Clontarf, Dublin 3 (IE).

(74) Agents: **O'BRIEN, John, A.** et al.; c/o John A O'Brien & Associates, Third Floor, Duncairn House, 14 Carysfort Avenue, Blackrock, County Dublin (IE).

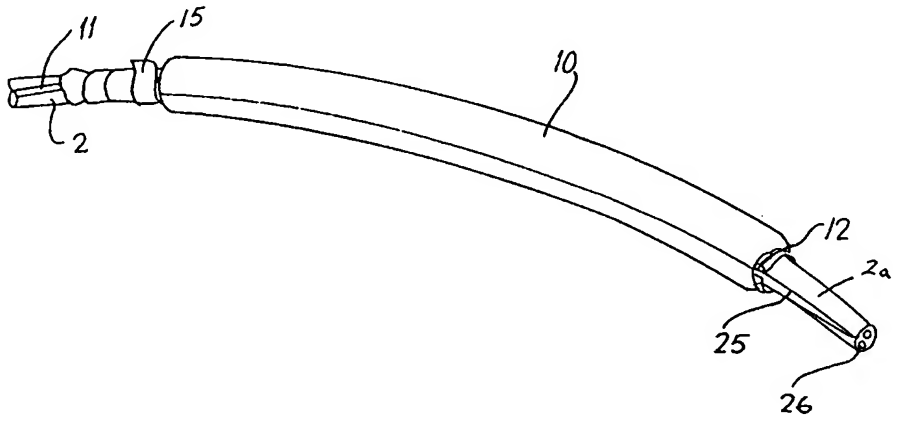
(81) Designated States *(national)*: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DE (utility model), DK, DK (utility model), DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW.

(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *with international search report*

[Continued on next page]

(54) Title: AN INSERTION DEVICE FOR AN ENDOSCOPE



(57) Abstract: A probe system comprises an inflatable guide device (10) and a colonoscope (2). The guide device (10) comprises a sleeve of pliable material inverted upon itself to form an evertable tube with an inflation part for connection to an inflation tube (11). A leading edge of the guide device (10) is releasably secured to the colonoscope (2) during insertion into a colon. After insertion the leading edge is released and the guide device (10) is inflated. The colonoscope (2) may then be advanced through the colon in a spaced relationship to the walls of the colon by an everting motion of the guide device (10).

WO 01/70096 A1

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

AN INSERTION DEVICE FOR AN ENDOSCOPE

Introduction

The invention relates to a probe system to assist the navigation of tortuous sections of a lumen or passageway.

The term probe refers to any instrument for delivery to a site of interest, for example in a body cavity. The instrument may be for examination, diagnosis or treatment such as a visualisation device, especially an endoscope. The endoscope is preferably a medical endoscope such as a colonoscope, gastroscope, enteroscope or the like.

Modern colonoscopes consist of a control section attached to a long flexible shaft with a steerable tip. The flexible shaft carries several tubes for light, air, water and suction. Light is transmitted through non-coherent fibre-optic bundles and images are transmitted from a miniature CCD TV camera positioned on the tip of the colonoscope. In some cases a biopsy channel with a larger bore to allow therapeutic procedures to be performed is also provided.

A control mechanism is used to steer the colonoscope through the colon using control wheels at the proximal external end of the colonoscope. There are usually two wheels: one for lateral control and the other for vertical control. These control wheels are attached to guide wires that extend through and are attached to the tip of the colonoscope. The colonoscope is typically 100-150 centimetres long and must be pushed from the distal end and guided through tortuous passages using external manipulation. Applying torque to the colonoscope can also assist in advancing it past bends in the colon.

The lower gastrointestinal tract comprises the rectum and the large intestine or colon. The colon, in a textbook arrangement of its anatomy, extends upwards from the lower right quadrant, traverses the width of the body just below the diaphragm, travels downwards along the left side of the abdomen and then loops in an anterior retrograde manner before linking up with the rectum and the anus. Even in such a textbook arrangement, the large intestine is difficult to cannulate with a colonoscope due to the flexible nature of the shaft of the instrument and the floppy nature of the colon. This is even more difficult with the more realistic anatomies of actual people. In some people the sigmoid colon can be very long and is unfixed, except by its mesentery, and so can be extremely difficult to cannulate due to its predisposition to form loops when a colonoscope is pushed through it. Some anatomical landmarks, such as the recto-sigmoidal junction, the splenic flexure and the hepatic flexure, are also difficult to pass through simply because of their tortuous nature. Looping of the colonoscope within the sigmoid colon exacerbates the problems in traversing these areas.

Normally the act of inserting the colonoscope through the sigmoid colon causes it to stretch out the redundant sections of the colon. A loop often forms, the size of which is limited only by the degree to which the mesentery will stretch. The presence of this loop often reduces the ability of the endoscopist to proceed much further than to the descending colon. Attempts to pass through the splenic flexure will often simply cause the sigmoid loop to increase in size, stretch the mesentery and cause considerable pain and discomfort to the patient. The loop can sometimes be removed by making the redundant bowel contract into a shorter segment, like the bellows of an accordion or concertina, giving the walls of the sigmoid colon a corrugated appearance. This is accomplished by several techniques known to those skilled in the art of lower gastro-intestinal (GI) endoscopy. Unfortunately, further pushing of the colonoscope into the colon can cause the loop to re-form.

In view of these problems it is not surprising that colonoscopy is a difficult technique that can only be mastered after performing many hundreds of examinations. The ability to speedily cannulate the bowel and traverse the entire colon all the way to the caecum is a skill that is only enjoyed by a minority of endoscopists. Published research on the subject of difficulty encountered in colonoscopy shows that the procedure fails in up to 15% of cases where failure is defined as inability to reach or visualise the caecum. Up to 35% of cases are considered to be difficult as defined by extended duration of the procedure and experience of pain by the patient. Other research shows that up to 29% of cases are considered to be technically difficult.

More generally there is a need for a probe system that may be used in a wide range of applications. For example, there is a need for a visualisation system for use in endoscopy. In the case of upper gastrointestinal tract endoscopy it is desired to examine the proximal small intestine or duodenum. Conventionally, this involves passing an endoscope through the oesophagus and stomach and into the duodenum. The large cavernous space in the stomach often permits the endoscope to loop, thus hindering further progress into the duodenum.

There is therefore a need for a device which will facilitate such a procedure to be performed more easily and efficiently.

Statements of Invention

According to the invention there is provided a probe system comprising a probe and a guide device for delivering the visualisation device to a target site, the guide device comprising a sleeve of pliable material having an inner sleeve portion and an outer sleeve portion that are interconnected to provide an evertable elongate tube, the tube having an inflation port for inflation of the tube

from an uninflated insertion configuration to an inflated guiding configuration in which the inner sleeve portion defines a lumen for guiding the probe to a target site in spaced-apart relation to the outer sleeve portion.

In a preferred embodiment of the invention the probe is an endoscope.

In one embodiment the probe device is a colonoscope.

In a particularly preferred embodiment the system comprises a releasable fastener for securing a leading end of the sleeve to the probe device in the insertion configuration of the guide device.

It is preferred that the system comprises a fixing for fixing a trailing end of the guide device to the probe. In this case the fixing may preferably comprise an adhesive tape, or interengagable formations such as a hook and pile type material.

In another embodiment the releasable fastener comprises a drawstring. Ideally the drawstring extends rearwardly through the sleeve and/or the visualisation device for manipulation thereof.

In one embodiment the system comprises a releasable clamp for releasably engaging the releasable fastener. Typically the releasable clamp comprises a forceps.

In one embodiment the releasable fastener is of a resilient material which is releasable on inflation of the sleeve. In this case preferably the releasable fastener comprises a resilient band.

In a preferred embodiment the system comprises a connection between the inflation part and an inflation source. The inflation source may be a source of inflation fluid such as an inert gas, for example air, or a suitable liquid.

In a preferred embodiment the probe has a tip which extends distally from the guide device.

In another aspect the invention provides a method for carrying out an examination and/or a treatment and/or a diagnostic procedure comprising the steps of:-

providing a probe and an inflatable guide device for the probe, the guide device having an inner sleeve portion and an outer sleeve portion;

introducing the probe with the guide device uninflated through an opening ;

advancing the guide and the uninflated guide device;

inflating the guide device to space the probe apart from the outer sleeve portion of the guide device;

advancing the probe device;

deflating the guide device; and

removing the guide device and probe from the opening.

In one preferred embodiment of the invention the probe comprises an endoscope.

In a further aspect the invention provides a method for carrying out a colonoscopy comprising the steps of:-

providing a colonoscope and an inflatable guide device for the colonoscope;

introducing the colonoscope with the guide device uninflated into the colon;

advancing the colonoscope and uninflated guide device to the start of the descending colon;

inflating the guide device to bridge the sigmoid colon;

advancing the colonoscope through the colon;

deflating the guide device; and

removing the guide device and colonoscope from the colon.

In one embodiment of the invention during advancement of the colonoscope and the uninflated guide device to the start of the descending colon, the sigmoid colon is collapsed.

In a preferred embodiment the guide device is an evertable sleeve which on inflation, everts to facilitate advancing the probe.

Preferably the method comprises the step of releasably fastening the guide device to the probe adjacent a leading end of the guide device on insertion of the guide

device. In this case preferably the method includes the step of releasing the fastening means to allow the guide device to evert.

The system assists in the passage of a probe through a passageway by preventing the formation of loops. The system also provides a substantially friction-less passage for a probe through a passageway.

The device consists of a sleeve of pliable material inverted upon itself and sealed at the end thus forming an evertable tube. There is an inflation port to allow for inflation with gas or fluid. The uninflated device is placed over the probe and is positioned so that its leading or distal end is just behind a steerable tip of the probe. This is to prevent the system from interfering with the steering of the probe. The guide device is typically 50 centimetres long but can be made in many other lengths. The guide device is secured at the proximal end of the probe by tape, or interengageable material such as hook and pile, and is releasably secured at the distal end by a releasable clamp. The release mechanism for the clamp may be passed through a biopsy channel of the probe. In the case of a colonoscope, the colonoscope with the device mounted on it in its uninflated state is inserted into the rectum as normal. The examination may then proceed in the normal manner. If a loop forms in the sigmoid colon it can be removed by contracting the redundant colon into an accordion or concertina configuration using known techniques.

When the tip of the colonoscope has reached the descending colon, and the distal end of the uninflated device has passed into the descending colon, and the sigmoid colon is in a non-looped, contracted state; the device is ready to be deployed. Activation of the device is achieved by inflating it such that it assumes a semi-rigid form. Inflation causes the device to expand whereby the outer walls of the device at least partially engage the inner walls of the corrugated colon and the inner lumen of the device firmly grips the colonoscope. In this manner the colonoscope is isolated from the walls of the colon thus removing the element of

friction that is responsible for expanding the corrugations in the colon and causing the formation of undesirable sigmoid loops. Subsequent attempts to insert the colonoscope further into the colon will cause the device to evert or roll out and allow the colonoscope to frictionlessly move through the colon without expanding the contracted sigmoid colon. Subsequently, the trailing end of the device will invert into the rectum through the anus with the colonoscope enveloped within it. Inversion of the proximal end and eversion of the distal end of the device will continue until the proximal end reaches the outer margins of the anus.

The device is mounted on the colonoscope in such a manner that its proximal end is permanently secured to the endoscope. This is achieved by the use of adhesive tape or hook and loop pile fasteners.

To prevent the uninflated device from crumpling while the colonoscope is being inserted into the colon during the initial phase of the colonoscopy, it is secured or clamped at its distal end, which is the end just behind the steerable tip of the colonoscope. The mechanism employed to secure or clamp the device is releasable so that the device can be permitted to evert at the appropriate time.

In one embodiment the release mechanism consists of a drawstring that is threaded through loops at the top of the device and back down through the biopsy channel of the colonoscope. Both ends of the thread exit from the opening of the biopsy channel on the control head of the colonoscope where they are held manually until it is desired to release the distal end of the device. When it is desired to unclamp the distal end of the device to allow it to roll, the operator releases one end of the drawstring and the entire drawstring is withdrawn from the colonoscope through the biopsy channel.

In another embodiment, the release mechanism consists of a drawstring that is threaded through loops at the top of the device and back down through the biopsy channel of the colonoscope. One end of the drawstring is fixed to a forceps in the channel and the other end is held between the jaws of the forceps. When it is desired to unclamp the distal end of the device to allow it to roll, the operator opens the jaws of the forceps releasing one end of the drawstring. The forceps is then withdrawn out of the biopsy channel and with it the drawstring.

In another embodiment, the device release mechanism consists of a simple expandable band, such as a rubber band, that is placed over the distal end of the device to hold it in position on the colonoscope. The band is sufficiently tight to hold the device firmly in place during the insertion phase of a colonoscopy. However, when the device is inflated the inflation pressure can overcome the constrictive force of the band, which will expand, and allow the device to roll.

In yet another embodiment, the device release mechanism consists of a simple expandable band that is placed over the distal end of the device to hold it in position on the colonoscope. Similarly, this band is tight enough to hold the device in position before it is deployed. When the device is inflated the band slips off the round distal end of the device and remains on the colonoscope. This allows the device to roll as intended.

In yet another embodiment, the device release mechanism consists of a wide expandable band that covers the distal part of the device and extends from there onto the steerable tip of the colonoscope. In this manner the leading edge of the device is encapsulated by the release mechanism and is sealed from the environment of the colon. This will prevent the influx of liquid or other material into the gap between the device and the colonoscope. The band is tight enough to hold the distal part of the device in position on the colonoscope. When the device is inflated the band rolls off the rounded distal end of the device towards the steerable tip of the colonoscope. The band is preferentially placed into its

encapsulating position on the device and colonoscope using a specially designed sizing tool. This is a cylindrical tool that fits over the steerable tip of the colonoscope and extends down to the point at which the leading edge of the guide device should be positioned. The tool is employed by first placing the wide band onto it. This is achieved by rolling the wide band from each of its ends towards its centre and placing it onto the sizing tool. Then the steerable tip of the colonoscope is inserted into the sizing tool. The device is then slid up toward the colonoscope until its leading edge reaches the sizing tool. At this point the wide band is rolled onto the leading edge of the device and off the sizing tool. The sizing tool is removed and the distal end of the wide band is rolled towards the tip of the colonoscope thus encapsulating the leading edge of the device.

While the invention has been described with particular reference to a colonoscope it may also be applied more generally to any endoscope or indeed to any suitable probe.

Brief Description of the Drawings

The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which: -

Fig. 1 is a perspective view of a guide device according to the invention;

Fig. 2 is a perspective view of the device of Fig. 1 mounted to a colonoscope;

Fig. 3 is a cross sectional view of a distal end of the colonoscope of Fig.2;

Fig. 4 is a perspective view of the device of Fig. 2 inflated and mounted to the colonoscope of Fig. 2;

Fig. 5 is a perspective view of the device of Fig. 4 in another configuration of use;

Fig. 6 is a cross sectional view of the distal end of the colonoscope of Fig. 2 in another configuration of use;

Fig. 7 is a perspective view of the device of Figs. 1 to 6 in another configuration of use;

Fig. 8 is a schematic view of the major components of a large intestine, rectum and anus;

Fig. 9 is a front view of the device of Figs. 1 to 7, partially inserted and uninflated;

Fig. 10 is a front view of the device of Fig. 9 inserted through the entirety of the sigmoid colon;

Figs.11 and 12 are front views illustrating the reduction of the sigmoid colon;

Fig. 13 is a front view of the device inflated in the reduced sigmoid colon;

Fig. 14 is a front view of the inflated device of Fig. 13 moving through the sigmoid colon;

Fig. 15 is a perspective view of another guide device according to the invention in an uninflated configuration;

Fig. 16 is a perspective view of the device of Fig. 15 inflated;

Fig. 17 is a perspective view of the device of Fig. 16 in another configuration of use;

Fig. 18 is a perspective view of another guide device according to the invention in an uninflated configuration;

Fig. 19 is a perspective view of the device of Fig. 18 inflated;

Fig. 20 is a side, partially cross sectional view of another guide device according to the invention with an associated band applicator;

Figs. 21 to 25 are side, partially cross-sectional views showing the band being mounted to the guide device;

Fig. 26 is a side, partially cross-sectional view of the guide device of Figs. 20 to 25 in use; and

Figs. 27 and 28 are schematic views of a guide device according to the invention in another application.

Detailed Description

Referring to the drawings and initially to Figs. 1 to 7 thereof, there is illustrated a probe system according to the invention comprising a guide device 10 and a

probe such as a colonoscope 2. The guide device 10 comprises a sleeve of pliable material inverted upon itself and sealed at its end to form an evertable tube. The sleeve has an inflation port at its proximal end in communication with an inflation tube 11, and loops 12 are provided at a distal end of the sleeve through which a drawstring 25 may be threaded.

Figure 2 illustrates the guide device 10 in an uninflated configuration mounted onto the colonoscope 2, the colonoscope 2 having a distal tip 2a. The proximal end of the guide device 10 is secured to the colonoscope 2 using adhesive tape 15, or hook and pile fasteners. The distal end of the guide device 2 is releasably attached to a distal end of the colonoscope 2 by means of a drawstring 25 that is threaded through the loops 12 at the distal end of the guide device 10. The drawstring 25 extends from the distal end of the guide device 10 up to the tip 2a of the colonoscope 2 and passes back down through a central lumen 26 of the colonoscope 2, for example a biopsy channel.

Figure 3 illustrates the mechanism by which the drawstring 25 is secured within the central lumen 26. In this embodiment a forceps 30 is provided within the central lumen 26 to clamp an end of the drawstring 25, the other end of the drawstring 25 being attached to the body of the forceps 30. To release the drawstring 25 the forceps 30 is operated by a proximal mechanism at a control section of the colonoscope 2. The forceps 30 may be activated in the same manner as a standard biopsy forceps used in endoscopy.

Figure 4 illustrates the guide device 10 in an inflated configuration mounted on the colonoscope 2. The proximal end is secured with tape 15 (adhesive or hook and pile) and the distal end is secured by means of the drawstring 25 passing through the loops 12 and back through the central lumen 26 of the colonoscope 2.

Figure 5 illustrates the release of the drawstring 25 by opening the jaws of the forceps 30 in the central lumen 26 of the colonoscope 2 (Fig. 6). Releasing the distal end of the device 10 allows the guide device 10 to roll (Fig. 7). The forceps 30 may be totally withdrawn from the colonoscope 2 and with it the now-redundant drawstring 25.

Referring now to Fig. 8 there is illustrated the major components of a large intestine, rectum and anus. The anus A leads into the rectum B which in turns leads into the sigmoid colon C having a mesentery N. From the sigmoid colon C a start D leads to the descending colon E which leads to the transverse colon G. The transverse colon G is attached to a mesentery H and leads into the ascending colon J which terminates in the caecum K, to which the appendix L is attached. Two relatively acute bends exist between the transverse colon G and the descending E and ascending J sections and are referred to as the splenic F and hepatic I flexures respectively.

The ascending and descending sections of the colon J, E are generally fixed in position while the transverse and sigmoid portions G, C are partially mobile being attached to mesenteries H and N. The redundancy in the sigmoid colon C can be seen.

In use the guide device 10 is mounted to the colonoscope 2 in an uninflated configuration, and the colonoscope 2 is inserted through the anus A until the tip 2a is partially within the sigmoid colon C, as illustrated in Fig.9.

The colonoscope 2 is then inserted through the entirety of the sigmoid colon C until the tip 2a is at the proximal margin of the descending colon E (Fig. 10). The sigmoid colon C has formed a loop, the size of which is limited by the extent to which the sigmoid mesentery N will stretch. The sigmoid loop C is collapsed to reduce the sigmoid colon C into an accordion configuration by

manoeuvres described above and known to those skilled in the art (Fig.11). Fig. 12 illustrates the sigmoid colon C with a straight aspect following the reduction manoeuvre.

The guide device 10 is inflated to engage the inner walls of the sigmoid colon C, with the proximal part of the guide device 10 protruding externally from the anus A (Fig. 13).

The inflated guide device 10 may be rolled through the sigmoid colon C with the colonoscope 2 inside by pushing the colonoscope 2 distally which causes the proximal end of the guide device 10 to invert and the distal end to evert (Fig 14). The colonoscope 2 is spaced from the walls of the colon by the guide device 10. When inflated, the guide device 10 curves around the splenic flexure F and rolls further into the transverse colon G. Due to the nature of the rolling mechanism, the tip 2a of the colonoscope 2 travels twice the distance of the guide device 10 when pushed through the colon.

Referring now to Figs. 15 to 17 there is illustrated another guide device 20 according to the invention, which is similar to the guide device 10 of Figs. 1 to 14, and the same reference numerals are assigned to similar elements in Figs. 15 to 17. In this case an expandable fixing band 40 is attached to the distal end of the guide device 20. The band 40 applies sufficient constrictive force to hold the guide device 20 in position on the colonoscope 2 during the insertion and withdrawal phases of negotiating the sigmoid colon C. When the guide device 20 is inflated the inflation pressure overcomes the constrictive force of the expandable fixing band 40 (Figure 16) and the guide device 20 may then roll in the normal manner (Figure 17). Deflation of the guide device 20 causes the expandable fixing band 40 to re-tighten around the guide device 20.

Referring to Figs. 18 and 19 there is illustrated another guide device 30 according to the invention, which is similar to the guide devices 10, 20 of Figs. 1 to 17, and the same reference numerals are assigned to similar elements in Figs. 18 and 19. In this case an expandable fixing band 50 is attached to the distal end of the guide device 30. The band 50 applies sufficient constrictive force to hold the guide device 30 in position during the colonoscopy. When it is desired to allow the guide device 30 to roll it is inflated in the normal manner. This causes the expandable fixing band 50 to roll off the guide device 30 towards the tip 2a of the colonoscope 2 (Figure 19) allowing the guide device 30 to roll as intended.

Referring now to Figs. 20 to 26 there is illustrated a further guide device 64 according to the invention, which is similar to the guide devices 10, 20, 30 of Figs. 1 to 19, and the same reference numerals are assigned to similar elements in Figs. 20 to 26. In the arrangement of Figs. 20 to 26, the release mechanism is provided by a wide expandable band 61 which extends from the distal end of the guide device 64 to the steerable tip 2a of the colonoscope 2. The wide elasticated band 61 is placed into its encapsulating position on the guide device 64 and the colonoscope 2 using a band applicator 60 in the following manner.

The wide elasticated band 61 is rolled from each of its ends towards its centre and placed onto the band applicator 60. The band applicator 60 is a cylindrical tool that fits over the steerable tip 2a of the colonoscope 2 and extends back to the point at which the distal end of the guide device 64 should be positioned. Fig. 20 illustrates the uninflated guide device 64 mounted on the colonoscope 2 with the tip 2a extending distally from the distal end of the guide device 64. The band applicator 60 is shown with the rolled-up wide elasticated band 61 mounted on it. The band applicator 60 has a step 62 to locate the guide device 64 in a desired position.

The tip 2a is inserted into the band applicator 60 until it can go no further. The guide device 64 is then slid up to the positioning step 62 inside the band applicator 60 so that it assumes the correct displacement from the tip 2a of the colonoscope 2 (Fig. 21).

A proximal part 65 of the elasticated band 61 is rolled proximally onto the uninflated guide device 64 (Fig. 22). A distal part 66 of the wide elasticated band 61 is then rolled proximally back onto the uninflated guide device 64 so that that it is no longer situated on the band applicator 60 (Fig. 23). The tip 2a of the colonoscope 2 is then removed from the band applicator 60 (Fig. 24). The distal part 66 of the wide elasticated band 61 is rolled towards the tip 2a of the colonoscope 2, thus encapsulating the distal end of the guide device 64 (Fig. 25).

The leading edge of the guide device 64 is encapsulated by the release mechanism and is sealed from the environment of the colon. This will prevent the influx of liquid or other material into the gap between the guide device 64 and the colonoscope 2. The band 61 is tight enough to hold the distal part of the guide device 64 in position on the colonoscope 2.

When the guide device 64 is inflated, this causes the proximal part 65 of the wide elasticated band 61 to roll off the guide device 64 towards the tip 2a of the colonoscope 2 (Fig. 26), thereby releasing the guide device 64 to roll.

While the invention has been described primarily in relation to colonoscopy it will be apparent to those skilled in the art that the invention may be applied more generally to endoscopy. For example, the invention may be used in the practise of upper GI endoscopy when it is desired to examine the proximal small intestine or duodenum. This involves passing an endoscope through the oesophagus and stomach and into the duodenum. The large cavernous space in the stomach often permits the endoscope to loop, thus hindering further progress

into the duodenum. This is a similar situation to the case in colonoscopy. To resolve the problem the guide device according to the invention is anchored between two stable, fixed positions. In this case the distal end of the guide device is anchored at the pyloric valve and middle and proximal sections are anchored within the oesophagus. In this way the endoscope will be less likely to loop into the cavernous stomach when pushed from the mouth but will be translated through the device into the duodenum.

Referring to Fig. 27 there is illustrated a guide device 70 according to the invention in use in the upper gastrointestinal tract. The uninflated guide device 70 is mounted onto an endoscope 71 that has reached the proximal margin of the duodenum 72. The leading end of the guide device 70 is anchored within the pyloric sphincter 73 while the more proximal section of the guide device 70 is anchored within the oesophageal sphincter 74. The cavernous nature of the stomach 75 can also be seen.

Fig. 28 illustrates the inflated guide device 70 anchored within the oesophageal and pyloric sphincters 74, 73 at the proximal and distal ends of the stomach 75. To progress the endoscope 71 further into the duodenum 72 the endoscope 71 is rolled within the guide device 70 in a manner similar to that described previously with reference to Figs. 13 and 14.

The endoscope 71 may thus be advanced into the duodenum 72 without forming a loop in the cavernous stomach 75.

The invention is not limited to the embodiments hereinbefore described which may be varied in detail.

CLAIMS

1. A probe system comprising a probe and a guide device for delivering the probe to a target site, the guide device comprising a sleeve of pliable material having an inner sleeve portion and an outer sleeve portion that are interconnected to provide an evertable elongate tube, the tube having an inflation port for inflation of the tube from an uninflated insertion configuration to an inflated guiding configuration in which the inner sleeve portion defines a lumen for guiding the probe to a target site in spaced-apart relation to the outer sleeve portion.

2. A system as claimed in claim 1 wherein the probe is an endoscope.

3. A system as claimed in claim 1 or 2 wherein the probe is a colonoscope.

4. A system as claimed in any preceding claim comprising a releasable fastener for securing a leading end of the sleeve to the probe in the insertion configuration of the guide device.

5. A system as claimed in any preceding claim comprising a fixing for fixing a trailing end of the guide device to the probe.

6. A system as claimed in claim 5 wherein the fixing comprises an adhesive tape, or interengagable formations such as a hook and pile type material.

7. A system as claimed in any of claims 4 to 6 wherein the releasable fastener comprises a drawstring.

8. A system apparatus as claimed in claim 7 wherein the drawstring extends rearwardly through the sleeve and/or the probe for manipulation thereof.

9. A system as claimed in any of claims 4 to 8 comprising a releasable clamp for releasably engaging the releasable fastener.

10. A system as claimed in claim 9 wherein the releasable clamp comprises a forceps.

11. A system as claimed in any of claims 4 to 7 wherein the releasable fastener is of a resilient material which is releasable on inflation of the sleeve.

12. A system as claimed in claim 11 wherein the releasable fastener comprises a resilient band.

13. A system as claimed in any preceding claim comprising a connection between the inflation part and an inflation source.

14. A system as claimed in claim 13 wherein the inflation source is a source of inflation fluid.

15. A system as claimed in any preceding claim wherein the probe has a tip which extends distally from the guide device.

16. A probe system substantially as hereinbefore described with reference to the accompanying drawings.

17. A method for carrying out an examination and/or a treatment and/or a diagnostic procedure comprising the steps of:-

providing a probe and an inflatable guide device for the probe, the guide device having an inner sleeve portion and an outer sleeve portion;

introducing the probe with the guide device uninflated through an opening ;

advancing the probe and the uninflated guide device;

inflating the guide device to space the probe apart from the outer sleeve portion of the guide device;

advancing the probe;

deflating the guide device; and

removing the guide device and probe from the opening.

18. A method as claimed in claim 17 wherein the probe comprises an endoscope.

19. A method for carrying out a colonoscopy comprising the steps of:-

providing a colonoscope and an inflatable guide device for the colonoscope;

introducing the colonoscope with the guide device uninflated into the colon;

advancing the colonoscope and uninflated guide device to the start of the descending colon;

inflating the guide device to bridge the sigmoid colon;

advancing the colonoscope through the colon;

deflating the guide device; and

removing the guide device and colonoscope from the colon.

20. A method as claimed in claim19 wherein during advancement of the colonoscope and the uninflated guide device to the start of the descending colon, the sigmoid colon is collapsed.

21. A method as claimed in any of claims 17 to 20 wherein the guide device is an evertable sleeve which on inflation, everts to facilitate advancing the probe.

22. A method as claimed in any of claims 17 to 21 including the step of releasably fastening the guide device to the probe adjacent a leading end of the guide device on insertion of the guide device.

23. A method as claimed in claim 22 including the step of releasing the fastening means to allow the guide device to evert.

24. A method for carrying out an examination and/or treatment and/or diagnostic procedure substantially as hereinbefore described with reference to the accompanying drawings.

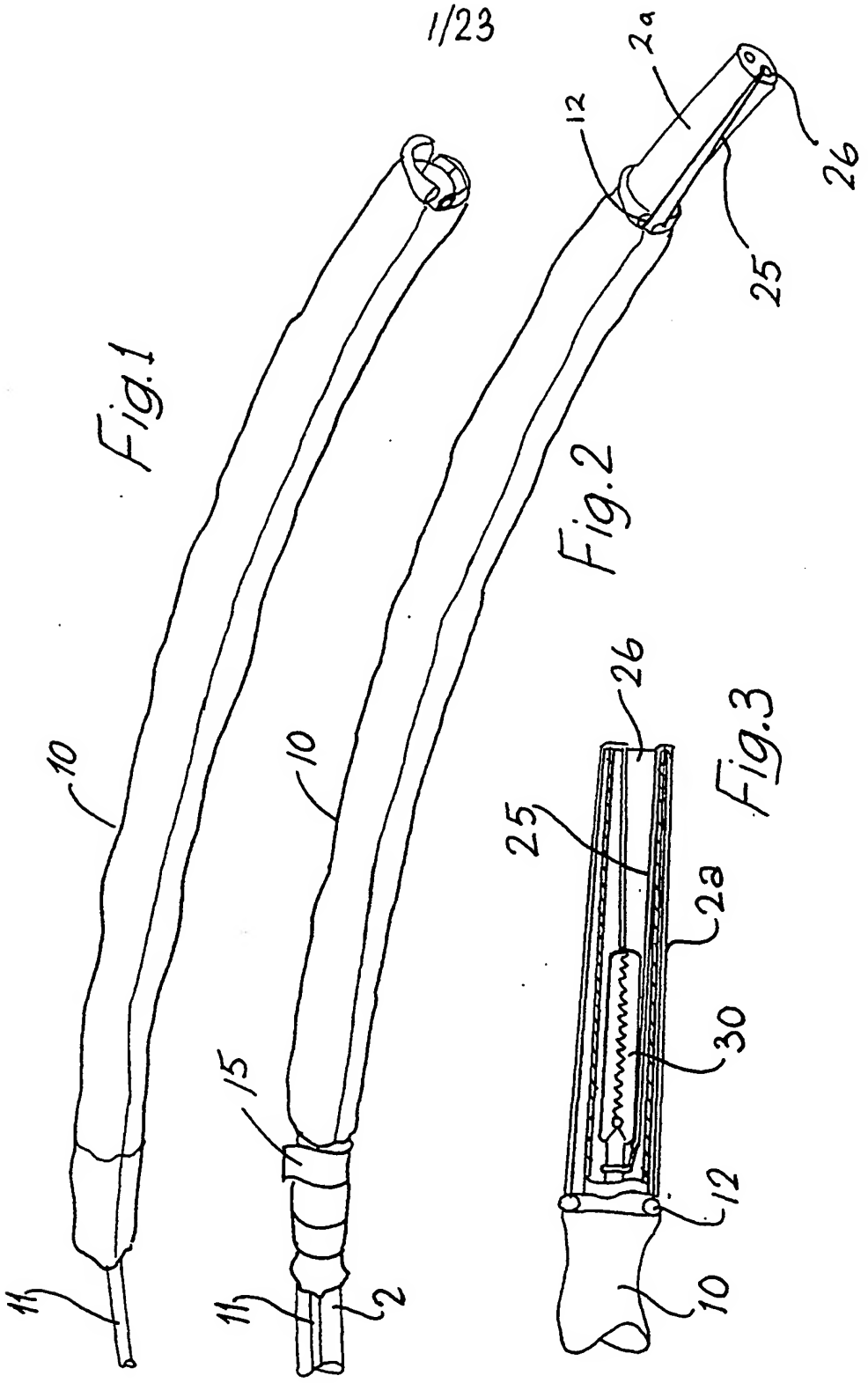


Fig.1
10
11
Fig.2
10
15
11
2
2a
12
26
25
Fig.3
26
25
2a
30
12
10

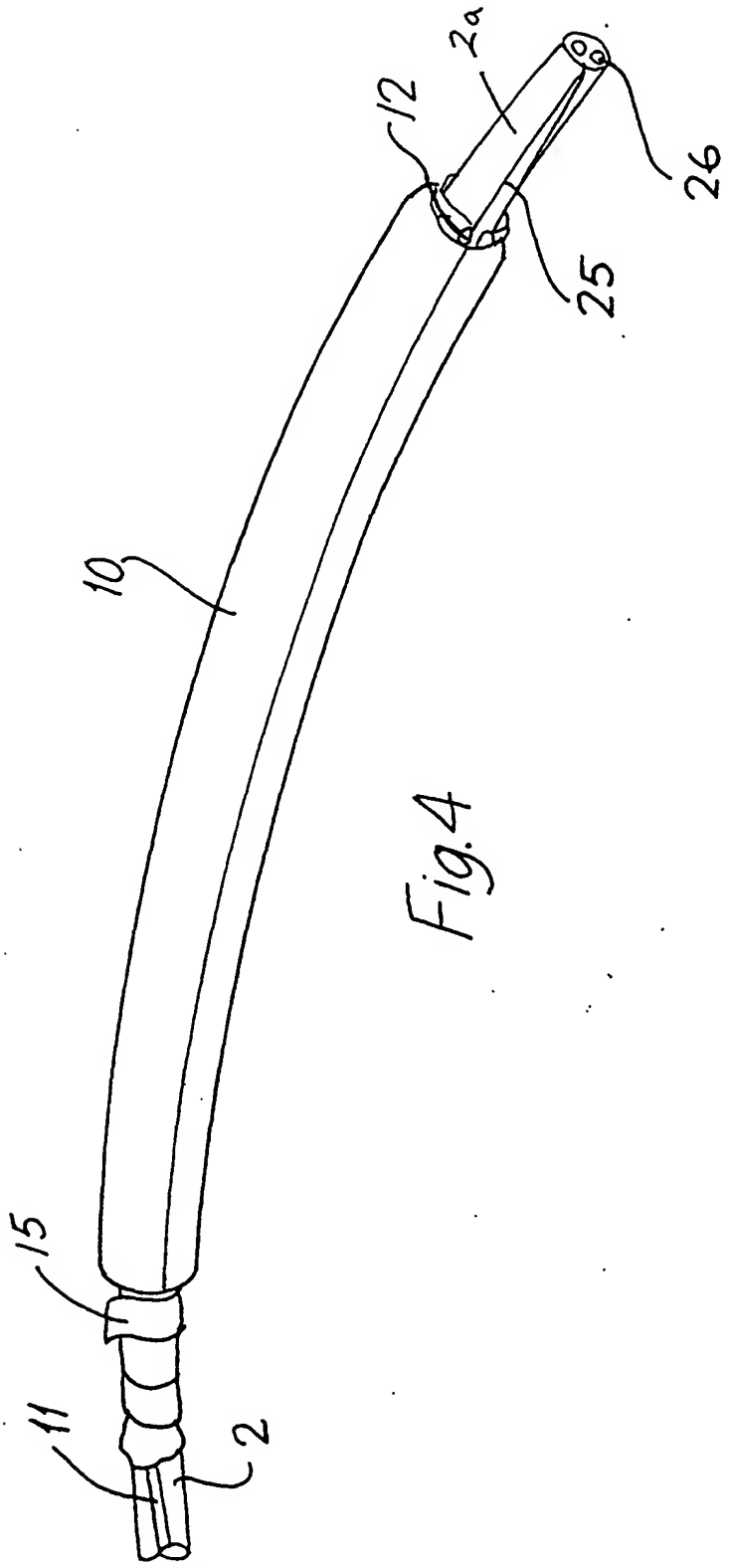


Fig.4

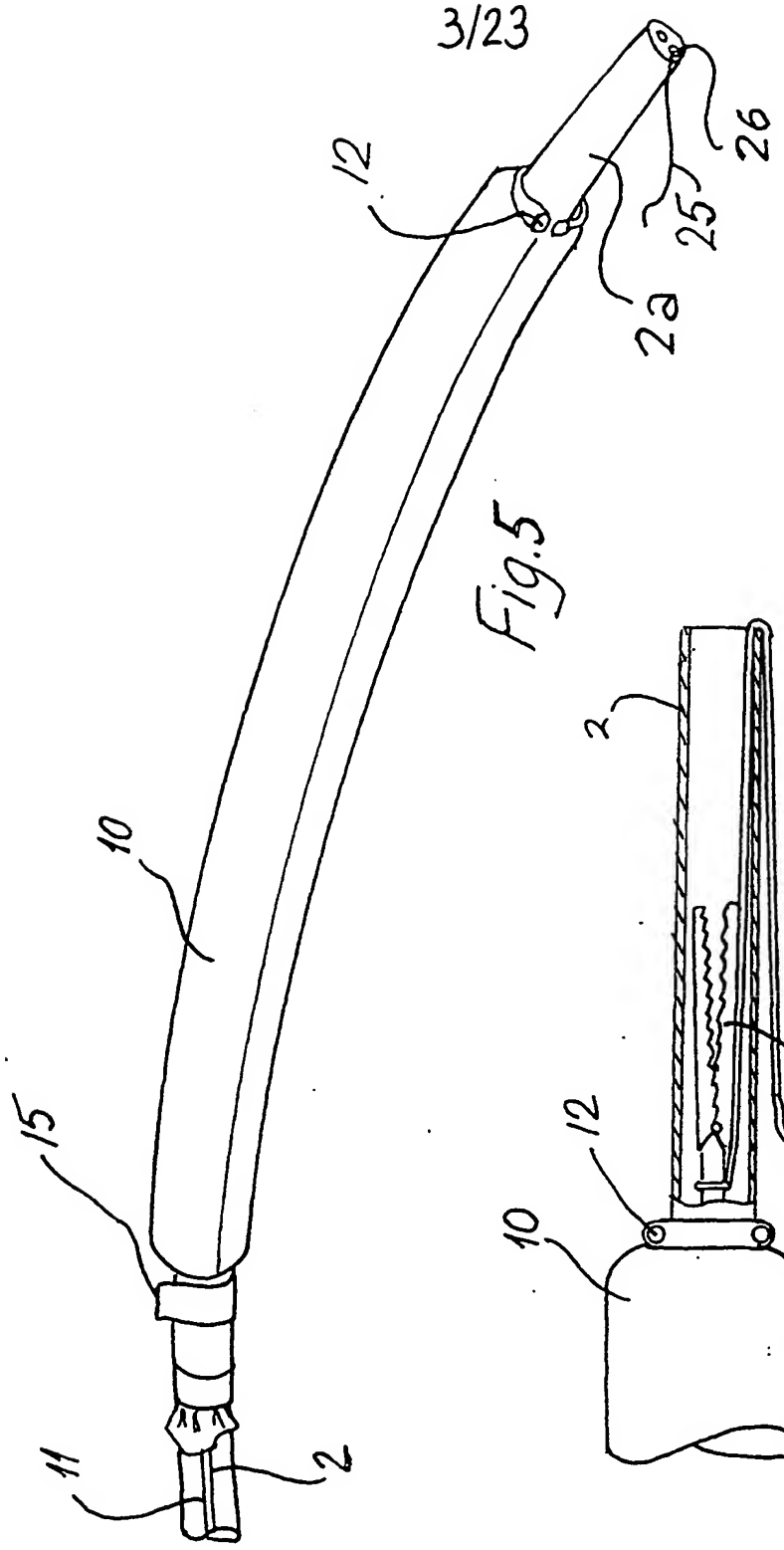


Fig.5

Fig.6

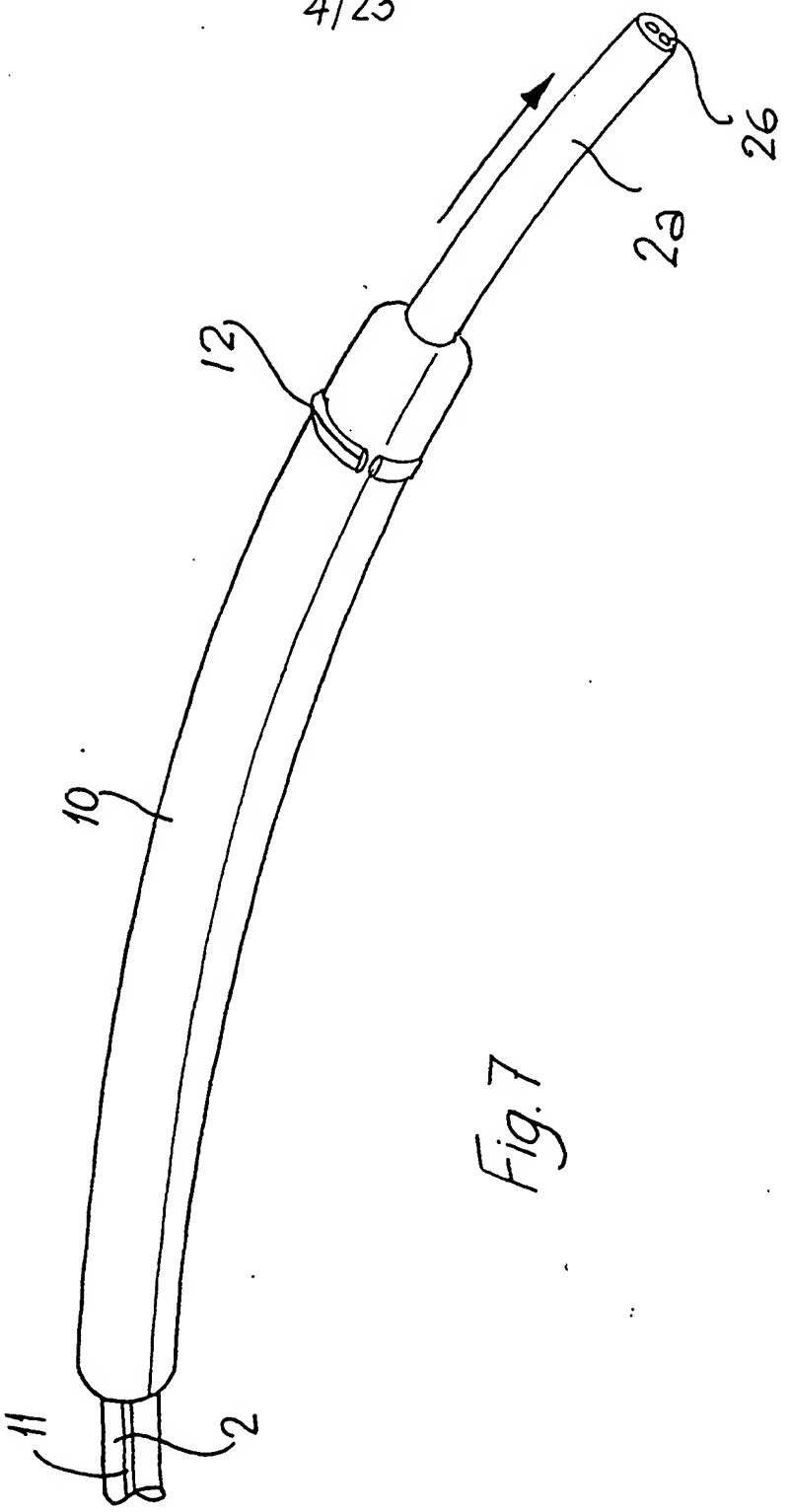


Fig. 7

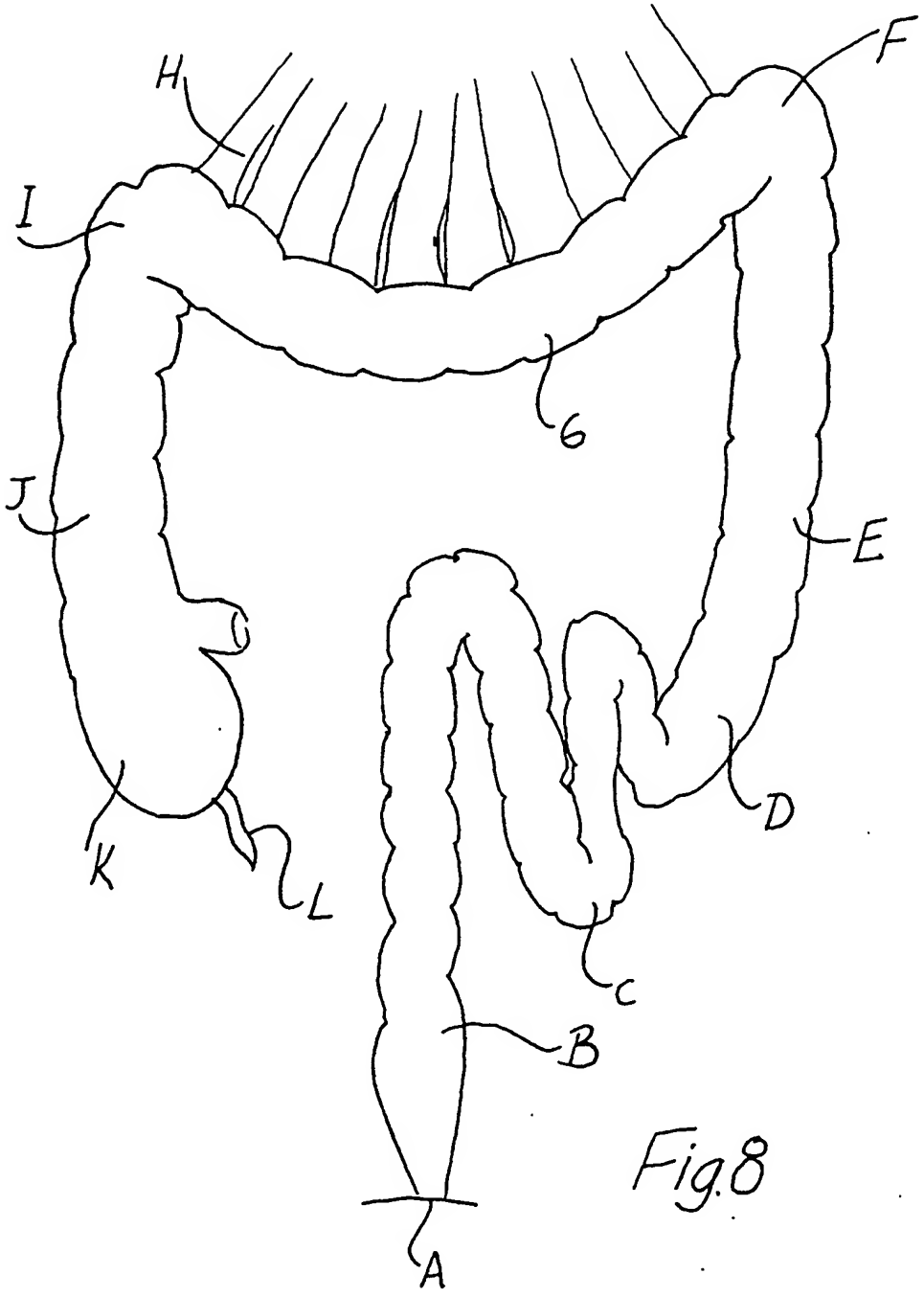


Fig.8

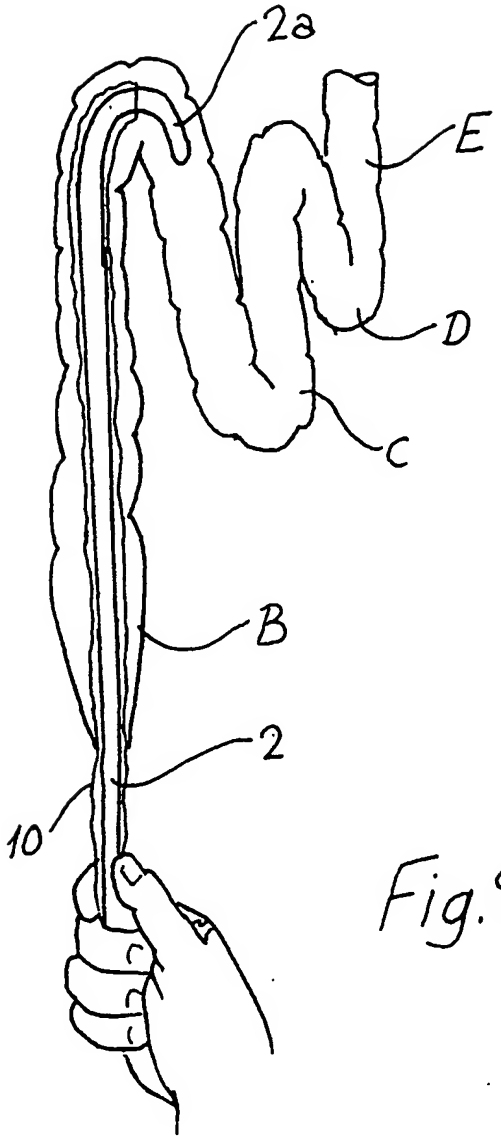


Fig.9

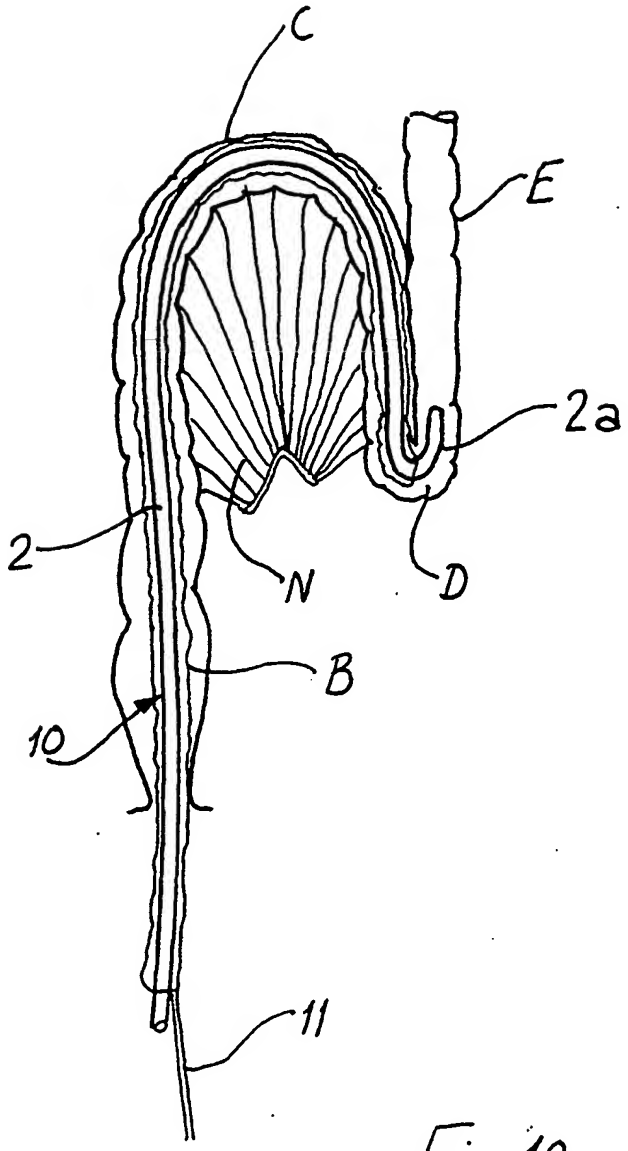


Fig. 10

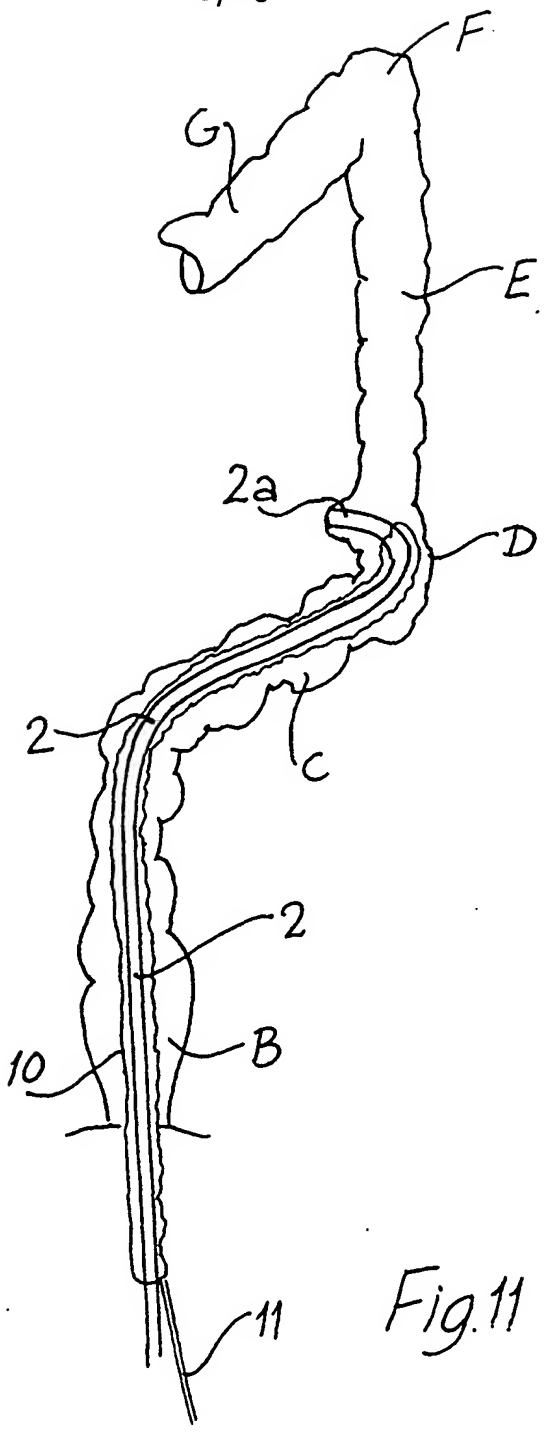


Fig.11

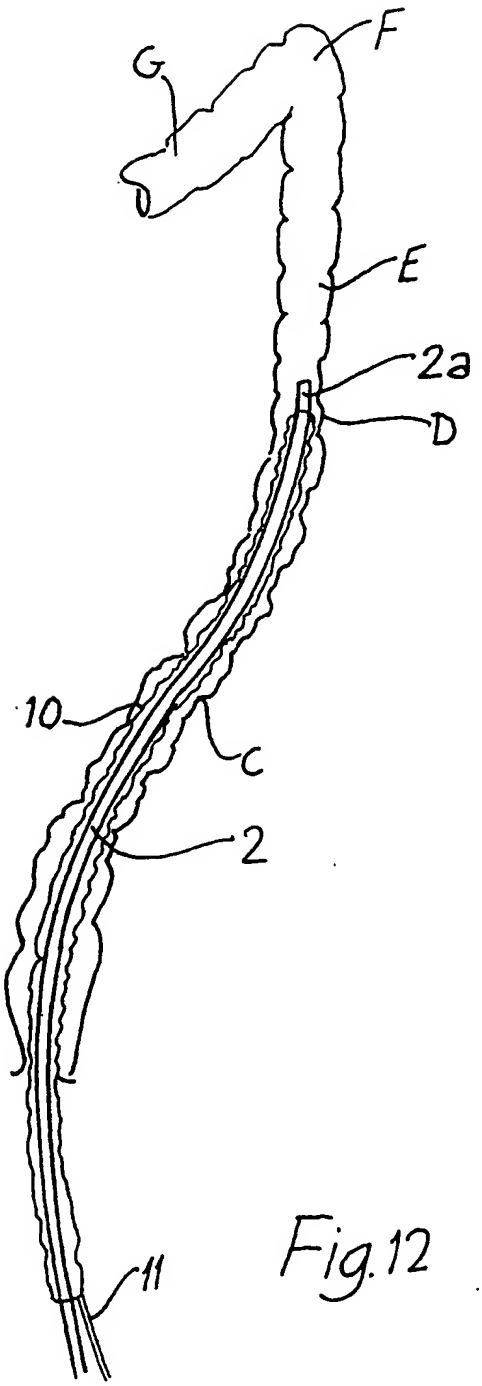


Fig. 12

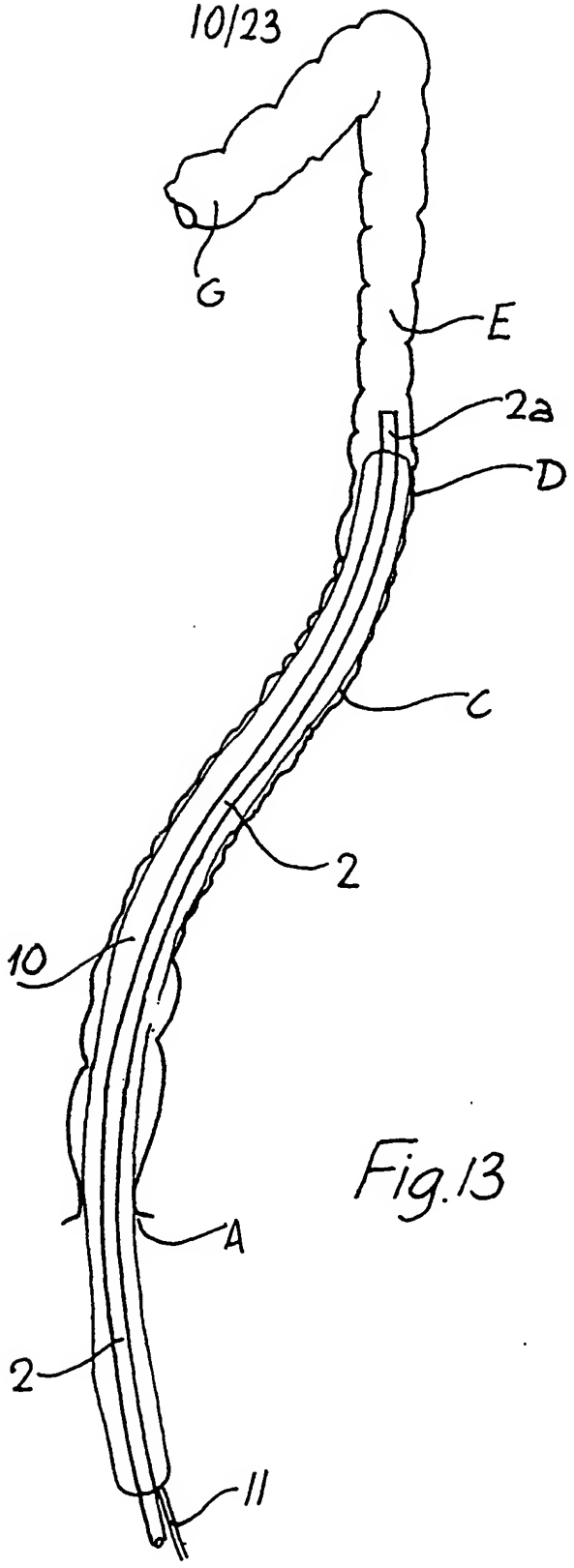


Fig.13

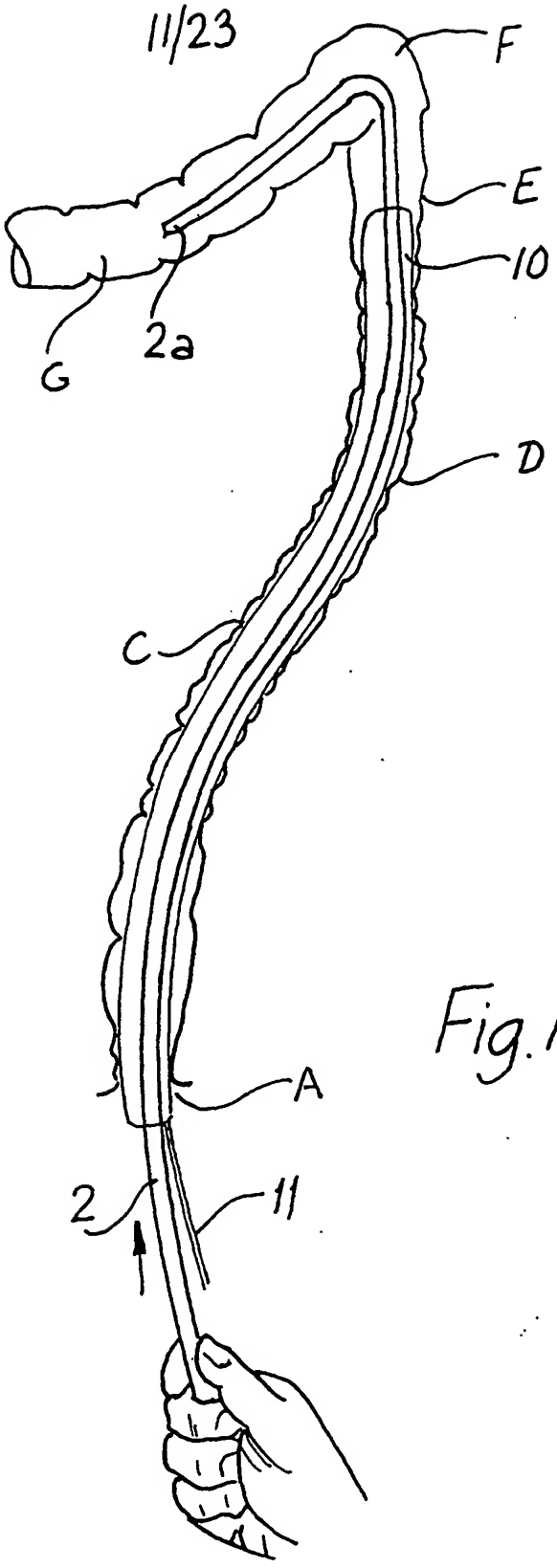


Fig. 14

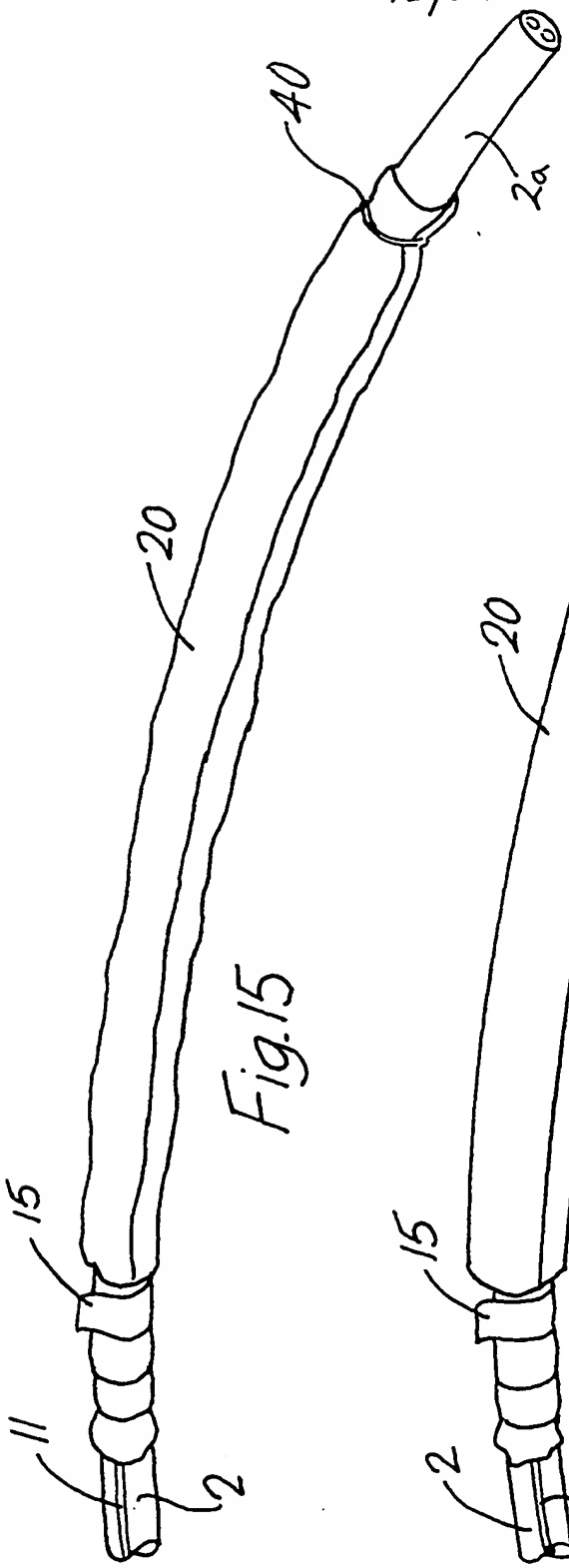


Fig.15

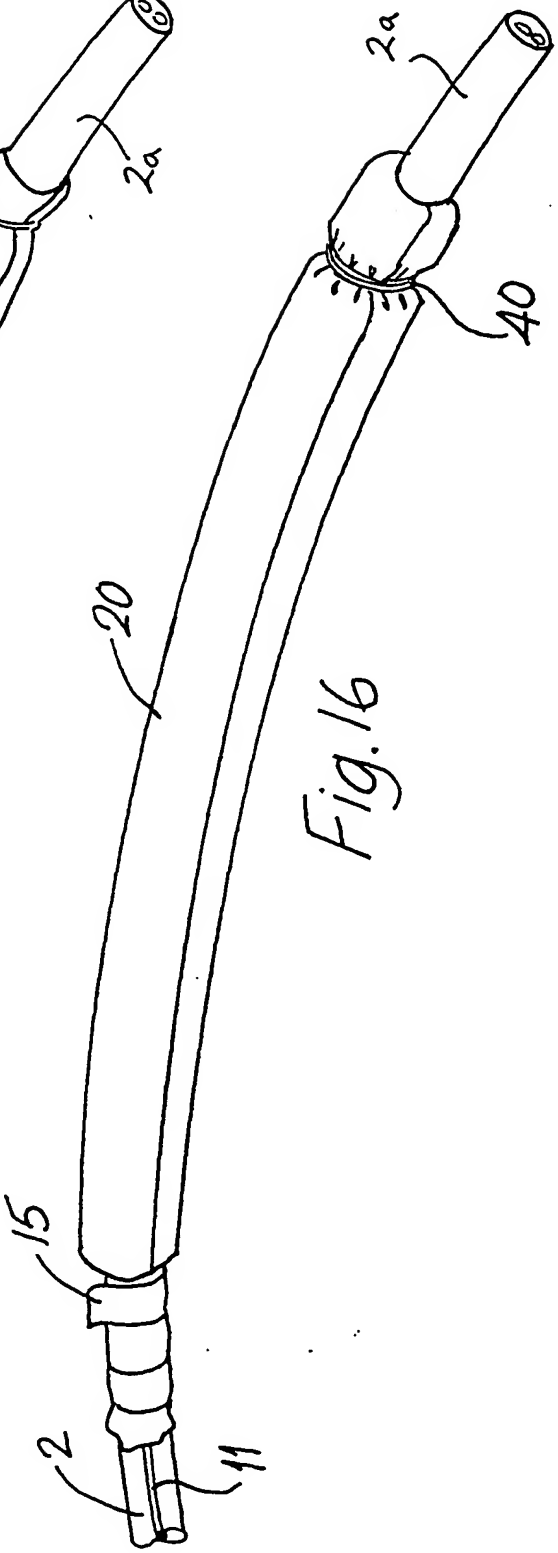


Fig.16

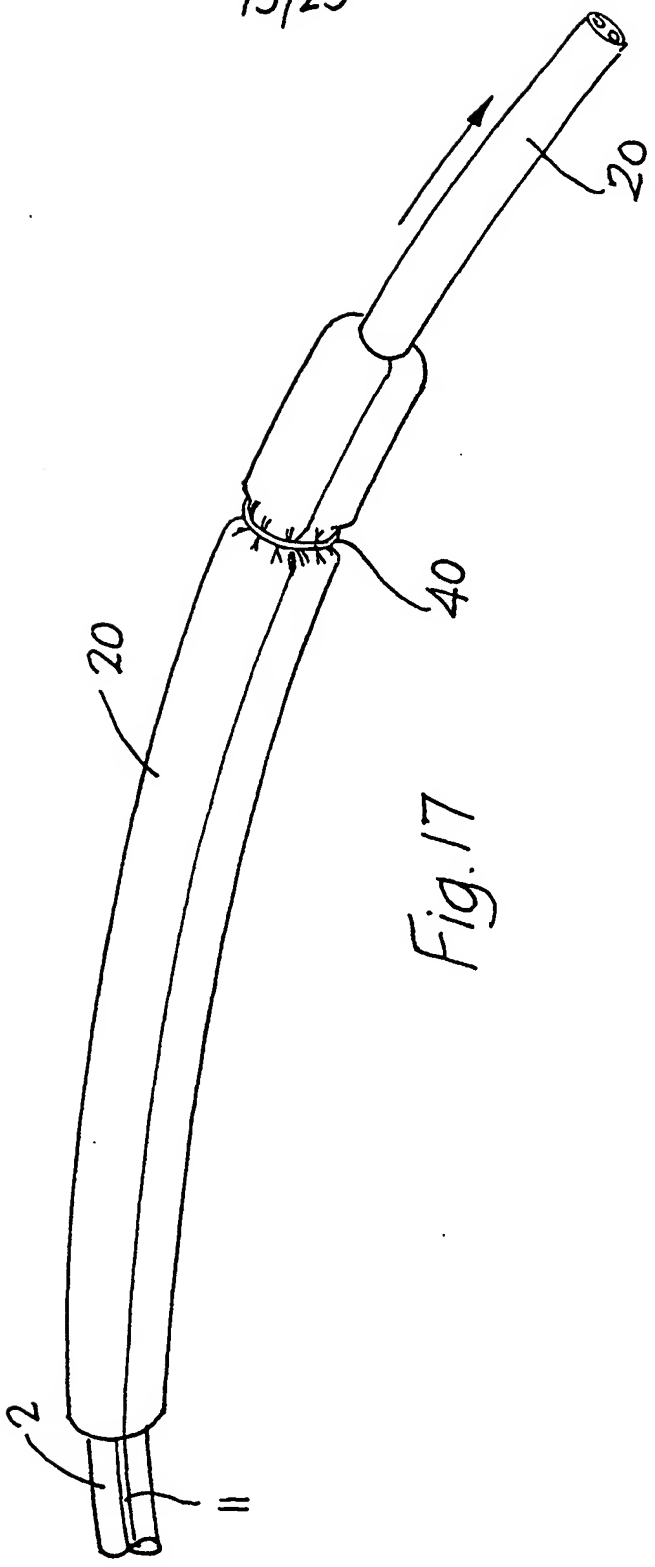


Fig. 17

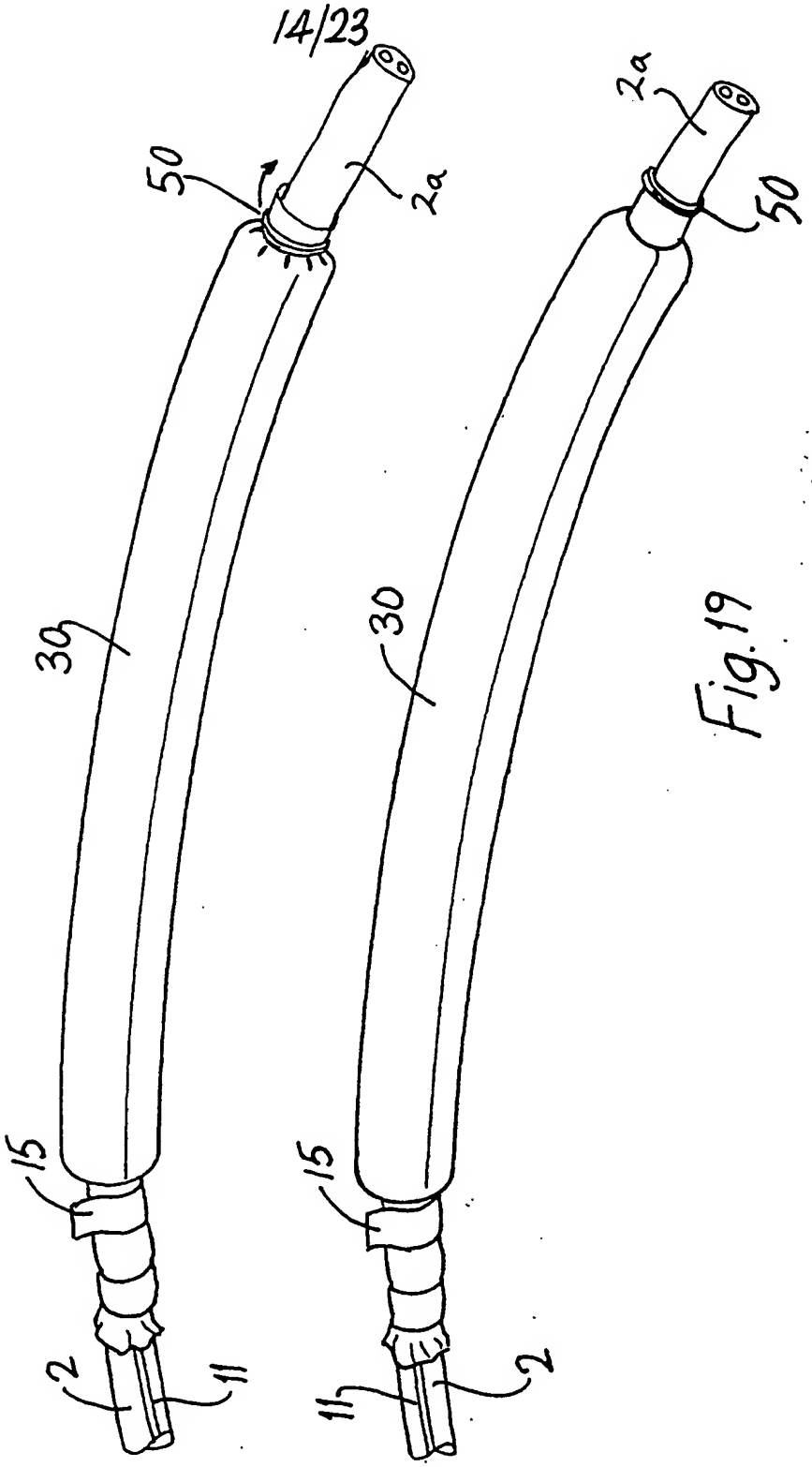


Fig. 19

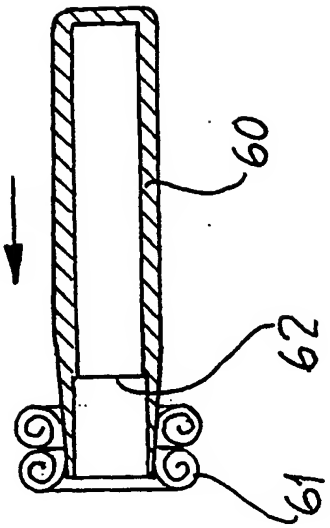
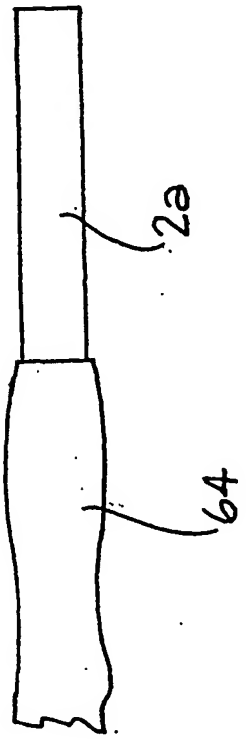


Fig. 20



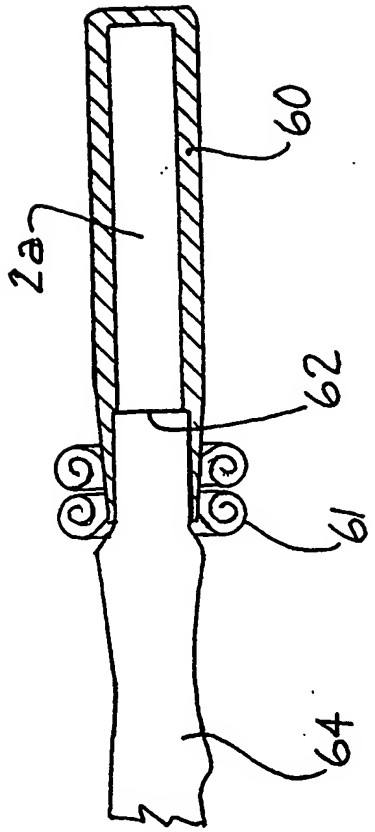


Fig. 21

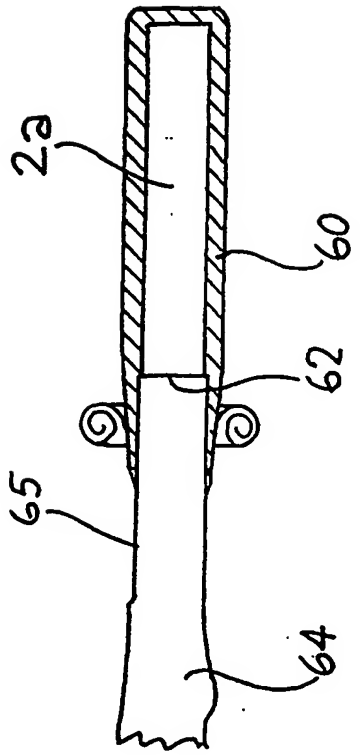


Fig.22

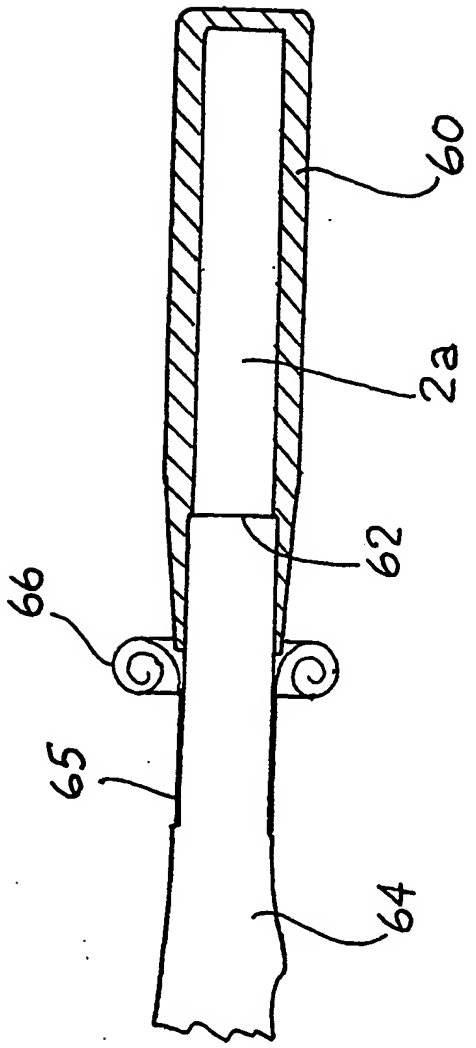


Fig.23

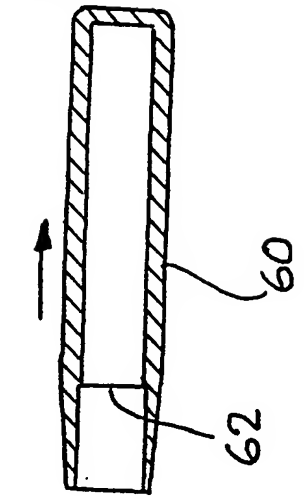
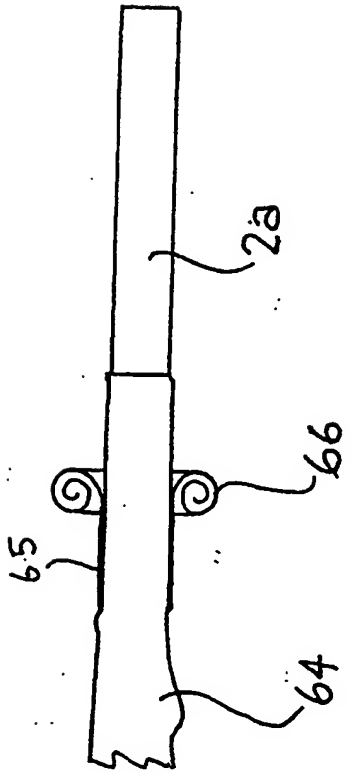


Fig. 24



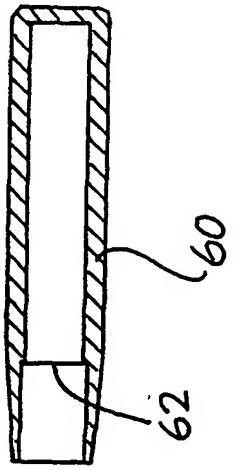
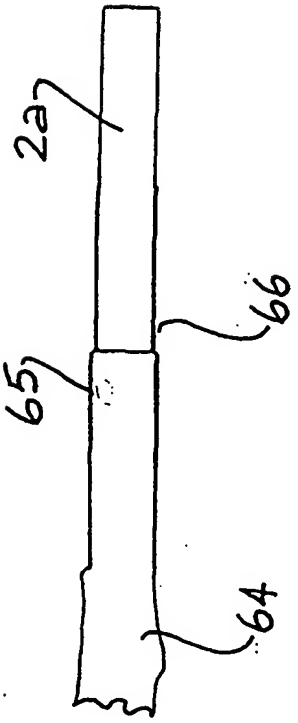


Fig. 25



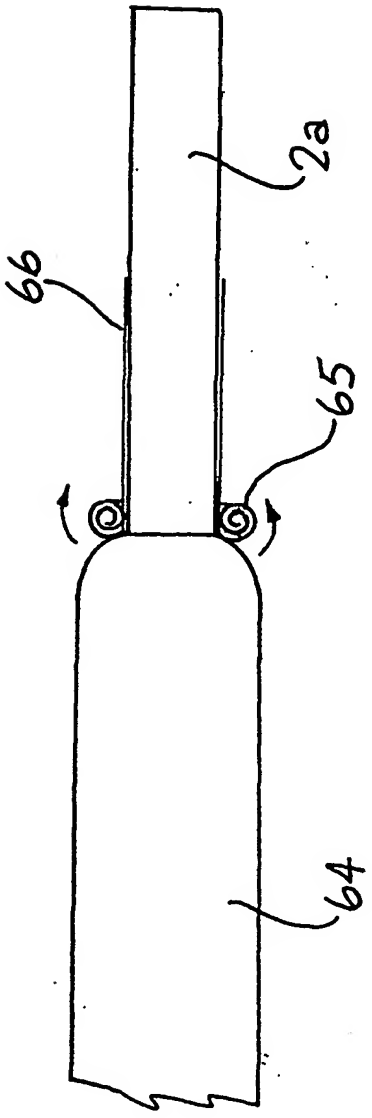


Fig. 26

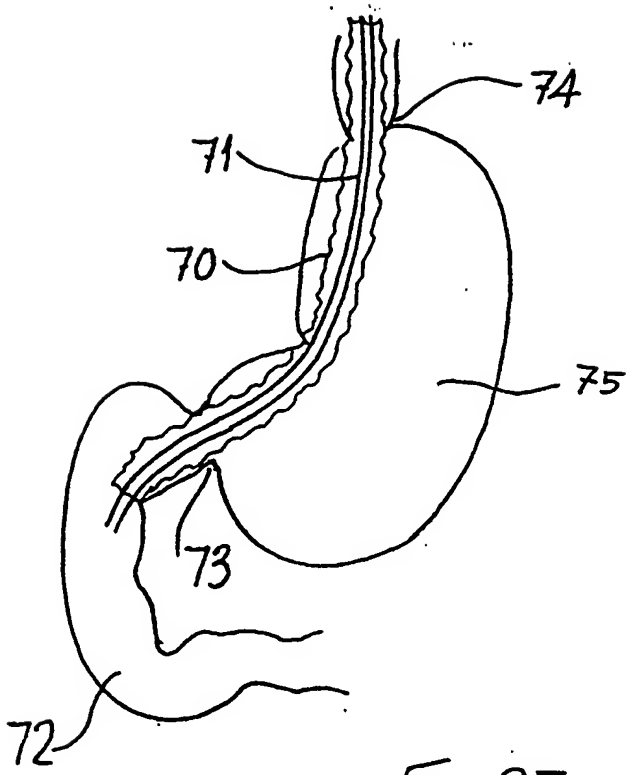


Fig. 27

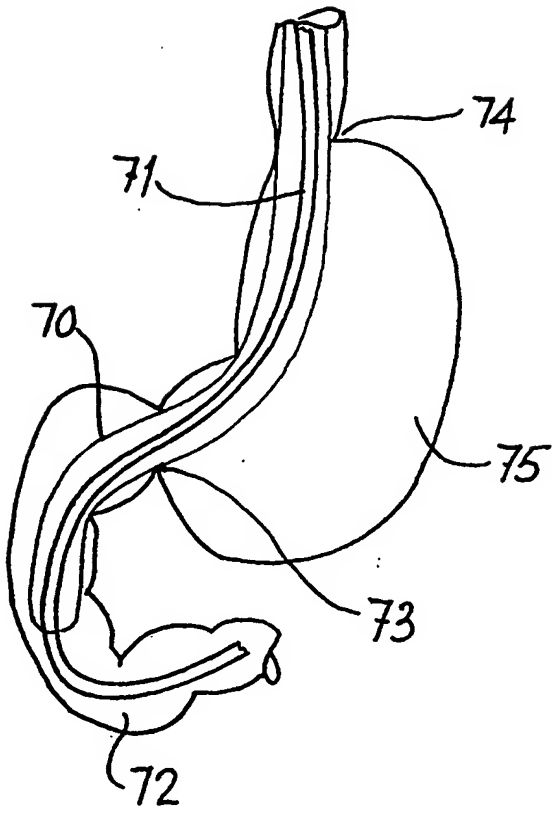


Fig. 28

INTERNATIONAL SEARCH REPORT

Inter nal Application No
PCT/IE 01/00038

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B1/01 A61B1/31

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)
EPO-Internal, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 92 00036 A (ENDOMED CORP) 9 January 1992 (1992-01-09) page 4, line 12-33; figures 32-34	1-3, 13-15
X	US 6 004 340 A (CO FRED H ET AL) 21 December 1999 (1999-12-21) abstract; figure 4 column 5, line 32 -column 6, line 1	1
P,X	WO 00 32119 A (YOUNG DEREK WILLIAM ;BONADIO FRANK (IE); REID ALAN (IE); ATROPOS L) 8 June 2000 (2000-06-08) abstract; figures 8,9 page 10, line 18 -page 11, line 15	1-3, 13-15
A	US 5 337 733 A (BAUERFEIND HERBERT ET AL) 16 August 1994 (1994-08-16) abstract; figures 3C,3D	1-3, 13-15

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
21 June 2001	29/06/2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Jonsson, P.O.

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inter ial Application No
PCT/IE 01/00038

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	PATENT ABSTRACTS OF JAPAN vol. 1995, no. 06, 31 July 1995 (1995-07-31) -& JP 07 075620 A (TOMOYUKI SATO), 20 March 1995 (1995-03-20) abstract figures 9-12	1-3, 13-15
A	PATENT ABSTRACTS OF JAPAN vol. 1999, no. 01, 29 January 1999 (1999-01-29) & JP 10 286222 A (OLYMPUS OPTICAL CO LTD), 27 October 1998 (1998-10-27) abstract	1-3, 13-15

Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inter tal Application No
PCT/IE 01/00038

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9200036 A	09-01-1992	AU 8200491 A	23-01-1992
		US 5236423 A	17-08-1993
US 6004340 A	21-12-1999	US 5702417 A	30-12-1997
		EP 1007136 A	14-06-2000
		WO 9840117 A	17-09-1998
		US 6179854 B	30-01-2001
		US 5893866 A	13-04-1999
		EP 0917480 A	26-05-1999
		JP 2000505672 T	16-05-2000
		WO 9804314 A	05-02-1998
		US 5993472 A	30-11-1999
		US 5944734 A	31-08-1999
		CA 2221614 A	21-11-1996
		EP 0957969 A	24-11-1999
		US 5951584 A	14-09-1999
		WO 9636388 A	21-11-1996
		US 5782854 A	21-07-1998
WO 0032119 A	08-06-2000	AU 1405400 A	19-06-2000
		AU 1405500 A	03-07-2000
		AU 1405600 A	19-06-2000
		WO 0032118 A	08-06-2000
		WO 0035356 A	22-06-2000
		AU 1405300 A	19-06-2000
		AU 1405700 A	19-06-2000
		WO 0032117 A	08-06-2000
		WO 0032120 A	08-06-2000
US 5337733 A	16-08-1994	DE 3935256 C	03-01-1991
		AT 99901 T	15-01-1994
		DE 4113265 A	12-03-1992
		DE 59004258 D	24-02-1994
		WO 9105507 A	02-05-1991
		EP 0497781 A	12-08-1992
		JP 5503434 T	10-06-1993
JP 07075620 A	20-03-1995	NONE	
JP 10286222 A	27-10-1998	NONE	